DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 2004

Bruce Lester, Ph.D.
Vice President, Research and Development
SterilMed, Inc.
11400 73rd Avenue North
MINNEAPOLIS MN 55369

Re: K012685 - Supplemental Validation Submission
Trade/Device Name: See Enclosed List
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: NLW
Dated: December 6, 2001
Received: December 7, 2001

Dear Dr. Lester:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on February 14, 2002. We have received your supplemental validation data as required for reprocessed single-use devices by the Medical Device User Fee and Modernization Act of 2002. After reviewing your supplemental validation data, we have determined the devices listed in the enclosure accompanying this letter are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market these devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA) they may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's applicable requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in classification for your devices and thus, permits you to legally market the devices. This letter will allow you to continue marketing the devices listed in the enclosure accompanying this letter.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment - Reprocessed Endoscopic Electrodes (K012685)

Karl Storz

26050 G
26050 J
26050 N
26050 NK
26050 NX
26050 NW
26050 L
26050 GR

Circon ACMI

VE-B
VE-F
VE-S
VE-LG
CE-24°
CE-26°
CE-28°
PE-24°
PE-26°
PE-28°
RB-24°
RB-26°
RE-24°
RE-26°
RE-28°
KE-24°
KE-26°
KE-28°
RAK-24°
RAK-26°
RAK-28°
RKE-24°
RKE-26°
RKE-28°
MLE-24-010
MLE-26-010
MLE-28-010
MLE-24-012
MLE-26-012
MLE-28-012
MLE-24-015

MLE-26-015
MLE-28-015
MLES-24-015
MLES-26-015

Indications for Use

510(k) Number (if known): K012685

Device Name: Reprocessed Endoscopic Electrodes

Indications For Use:

Reprocessed endoscopic electrodes are intended to be used for vaporization, ablation, coagulation and/or resection of soft tissue in the prostate and bladder as well as when ablation and coagulation are required in gynecological and urological surgical procedures.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012685

FEB 1 4 2002

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SECTION 2. SUMMARY AND CERTIFICATION

A. 510(k) Summary

Submitter:	SterilMed, Inc.
Contact Person:	Patrick Fleischhacker 11400 73rd Avenue North Minneapolis, MN 55369 Ph: 763-488-3400 Fax: 763-488-3350
Date Prepared:	August 13, 2001
Trade Name:	Reprocessed Endoscopic Electrodes
Classification Name and Number:	Active Electrosurgical Electrode Class II, 21 CFR 876.4300, and 21 CFR 884.4120 Panel 85
Product Code:	FAS, and HGI
Predicate Device(s):	Reprocessed endoscopic electrodes are substantially equivalent to the KSEA Vaporization Electrodes (K961702) manufactured by Karl Storz Endoscopy, and the Vaportrode Vaporization Electrodes (K890328B) manufactured by Circon/ACMI.
Device Description:	Reprocessed endoscopic electrodes are electrosurgical electrode devices that have a wide variety of tip configurations and sizes. The device is used to cut and cauterize prostate, bladder, gynecological, and urological tissue. They are used in conjunction with an endoscope and are powered by a separate RF generator. The RF generator component is not included in this submission; only the endoscopic electrodes are reprocessed.
Intended Use:	Reprocessed endoscopic electrodes are intended to be used for vaporization, ablation, coagulation and/or resection of soft tissue in the prostate and bladder as well as when ablation and coagulation are required in gynecological and urological surgical procedures.

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Functional and Safety Testing:

Representative samples of reprocessed endoscopic electrodes underwent bench testing to demonstrate appropriate functional characteristics. Process validation testing was done to validate the cleaning and sterilization procedures as well as the device's packaging. In addition, the manufacturing process includes visual and functional testing of all products produced

Conclusion:

Reprocessed endoscopic electrodes are substantially equivalent to the KSEA Vaporization Electrodes (K961702) manufactured by Karl Storz Endoscopy, and the Vaportrode Vaporization Electrodes (K890328B) manufactured by Circon/ACMI.

This conclusion is based upon the devices' similarities in functional design, materials, indications for use and methods of construction.